

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A pharmaceutical formulation essentially comprising

- a) an inner layer, which may where appropriate be applied to a core, with the active ingredient budesonide, bound in a binder
- b) an intermediate layer with a polymeric coating agent which is soluble in intestinal juice or extends release,
- c) an outer envelope which is resistant to gastric juice or an outer layer with a coating agent which is resistant to gastric juice

where the layers may comprise in a manner known per se further pharmaceutically usual excipients,

characterized in that

wherein the binder is a polymer or copolymer with acidic groups, and the formulation of the inner layer without intermediate and outer layer releases the bound active ingredient in the release test according to USP XXIII monograph <711> "Dissolution" with apparatus 2 (paddle) with 100 revolutions/min in phosphate buffer of pH 7.5 to the extent of more than 80% after 30 min.

Claim 2 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein characterized in that the polymeric binder is a (meth)acrylate copolymer which comprises 40 to 95% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 3 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, ~~wherein or 2, characterized in that~~ the polymeric binder is a vinylpyrrolidone/vinyl acetate copolymer.

Claim 4 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein one or more of claims 1 to 3, characterized in that the intermediate layer is a (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and no or up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 5 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein one or more of claims 1 to 3, characterized in that the intermediate layer is a (meth)acrylate copolymer which comprises 85 to 98% by weight free-radical polymerized units of C1- to C4-alkyl esters of acrylic or methacrylic acid and 15 to 2% by weight (meth)acrylate monomers with a quaternary ammonium group in the alkyl radical.

Claim 6 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein one or more of claims 1 to 5, characterized in that the outer coating agent which is resistant to gastric juice is a (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 7 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein ~~one or more of claims 1 to 5, characterized in that~~ the outer envelope which is resistant to gastric juice is a capsule.

Claim 8 (Currently Amended): The pharmaceutical formulation as claimed in claim 6, wherein characterized in that the capsule consists essentially of gelatin or of hydroxypropycellulose.

Claim 9 (Currently Amended): The pharmaceutical formulation as claimed in claim 6, wherein or 7, characterized in that the capsule is provided with a coating which is resistant to gastric juice.

Claim 10 (Currently Amended): The pharmaceutical formulation as claimed in claim 6, wherein 7 or 8, characterized in that it the pharmaceutical formulation comprises the active ingredient in the form of pellets or granules.

Claim 11 (Currently Amended): The pharmaceutical formulation as claimed in claim 1, wherein ~~one or more of claims 1 to 10, characterized in that it the pharmaceutical formulation~~ is a multiparticulate pharmaceutical form with substantially uniform release of budesonide in the small intestine and in the large intestine, which comprises at least two different types of pellets, one type of pellet releasing the active ingredient predominantly in the pH range of the small intestine and the other predominantly in the pH range of the large intestine.

Claim 12 (Currently Amended): The pharmaceutical formulation as claimed in claim 11, wherein characterized in that the pellets are enclosed in a capsule comprising (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical. as claimed in one or more of claims 6 to 10.

Claim 13 (Currently Amended): The pharmaceutical formulation as claimed in claim 11, wherein characterized in that the pellets are in the form of a tablet in which the pellets have been compressed together with conventional excipients to give the tablet unit.

Claim 14 (Currently Amended): Process for producing a pharmaceutical formulation as claimed in claim 1, wherein one or more of claims 1 to 13, characterized in that firstly an inner layer a) in which budesonide is bound in a polymeric binder with acidic groups is produced in a manner known per se by spray application or melt processing, where the inner layer a) is where appropriate applied to a core, and subsequently the intermediate layer b) and the outer layer c) are applied in a manner known per se by spray application or melt processing.

Claim 15 (Currently Amended): The process for producing a pharmaceutical formulation as claimed in claim 14, wherein characterized in that a binder comprising a (meth)acrylate copolymer which comprises 40 to 95% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical as claimed in claim 2 is employed in the form of a dispersion, and the inner layer a) is produced by aqueous spraying

of a budesonide-containing (meth)acrylate copolymer dispersion onto cores, with binding of the budesonide after evaporation of the water.

Claim 16 (Currently Amended): A method for treating ulcerative colitis, Crohn's disease and/or other disorders of the gastrointestinal tract which can be treated with budesonide, which comprises:

administering to a patient in need thereof an effective amount of the pharmaceutical formulation as claimed in claim 1. The use of a pharmaceutical formulation as claimed in one or more of claims 1 to 13 as pharmaceutical form for the therapy of ulcerative colitis, Crohn's disease and/or other disorders of the gastrointestinal tract which can be treated with budesonide.